Marked-up versions of the replacement paragraphs are provided in Appendix A. No new matter is introduced by the amendments to the specification.

REPLY

Applicants respectfully request that subsequent correspondence contain clarification with respect to subject matter of the Advisory Action. Applicants further request that consideration of the following arguments and evidence accompany consideration of the 01/03/02 Reply.

The Examiner has maintained new matter rejection of claims that recite, or are dependent on claims that recite the term "intestinal defect phenotype" and has written:

> "...regarding the term "intestinal defect phenotype," applicants arguments are not persuasive. It is noted that intestinal defect phenotype is not an art recognized term and that the specification does not define as to what phenotypes would be encompassed by the term. Furthermore, none of the sections of the specification or claims as quoted by the applicants in their response describes the term or uses the term. Applicants citation of the MPEP 2163.07 is inappropriate because the issue at hand is not a rephrasing of a passage, rather it is a new term that is not defined or disclosed in the specification."

Regarding the Examiner's assertion that the specification does not define what phenotypes would be encompassed by the term intestinal defect phenotype, applicants fail to understand the basis for this argument when the specification clearly describes several exemplary intestinal phenotypes. These include the pale pigmentation of the intestine (page 29 lines 28-30; page 46 lines 24-26), the reduction in number and size of pigmented droplets in the intestine (page 46 lines 29-30), the larger size and increased birefringence of gut granules in the intestine (page 47 line 1), and the unusual appearance of variably sized vesicles (page 47 lines 1-3).

The Examiner's assertion that use of the term intestinal defect phenotype is a new term, and not merely rephrasing and summarizing of what was disclosed in the specification (M.P.E.P. § 2163.07), appears to defy an abundance of evidence to the contrary. Thus, applicants again invite the Examiner's attention to originally filed claims, which read:

> 7. The animal of Claim 1 wherein said expression or mis-expression of said SREBP pathway protein results in an identifiable phenotype.
>
> 11. The animal of Claim 7 wherein said animal is a nematode and said identifiable phenotype is a pale intestine phenotype or other intestinal defect.

Applicants further invite the Examiner's attention to the results section of Example 3, page 46 lines 20-29:

> Germline ceSREBP (pin-1) RNAi produces several visible phenotypes in the progeny of the microinjected animals. ... Morphological defects in ceSREBP RNAi larvae (L1 and L2 stages) are confined to the intestine, where ceSREBP appears to be primarily expressed, and specifically affect three cytoplasmic structures in intestinal cells.

(Emphasis added in all quoted sections.) Applicants respectfully request clarification as to why the Examiner maintains that the term is not rephrasing.

Regarding the Examiner's assertion that the phrase is neither an art-recognized term nor specifically defined, applicants respectfully submit that a phrase need neither be explicitly defined, nor be an art-specific term, when the terms have readily understood and plain meaning. As set forth in M.P.E.P. § 2111.01, " ...the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification." Applicants do not understand why the Examiner ostensibly has not applied the common meaning of the individual words to reasonably interpret the phrase as meaning a trait comprising flaws in the intestine. The Examiner's apparent requirement for a definition (since the phrase is not a term of the art) contradicts the Written Description Guidelines promulgated by the PTO, which state:

> "The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, paragraph 1, for lack of adequate written description."

The Examiner's argument that the quoted sections of the specification and claims neither describe nor use the term intestinal defect phenotype seems to be based on the presumption that one reading the specification would not assume a correlation between recitation of an intestinal defect phenotype in the claims and the description of the specific defects referenced herein. Applicants respectfully disagree and submit that given the teachings of the application and the high level of skill in the art of *C. elegans* biology, including the understanding of *C. elegans* anatomy, the routine generation of genetic mutations, and identification of corresponding mutant phenotypes, one of skill of art would readily understand that the term "intestinal defect phenotype" encompassed the above-described phenotypes. Applicants note that the Examiner has not explained why he believes that one of ordinary skill would not view the described phenotypes as support for the term intestinal defect phenotype. On this matter, the Written Description Guidelines state:

> "If the examiner determines that the application does not comply with the written description requirement, the examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims."

Regarding the basis for claim terminology in the description, M.P.E.P. § 608.01(o) emphasizes that the meaning of every term used in the claims should be apparent for the descriptive portion of the specification and instructs that potential confusion may be rectified by amendment to the specification.

> "While an applicant is not limited to the nomenclature used in the application as filed, he or she should make appropriate amendment of the specification whenever this nomenclature is departed from by amendment of the claims so as to have clear support or antecedent basis in the specification for the new terms appearing in the claims."

For the reasons set forth above, applicants submit that the basis for the term "intestinal defect phenotype" is abundantly obvious. However, applicants would be willing to accept an Examiner's amendment to the specification that introduces this precise term. For instance, the paragraph that begins on page 46 line 27 could be amended to add a first sentence that reads: "A variety of intestinal defect phenotypes were observed."

Finally, the Examiner appears to separately consider new matter and written description rejections and has written:

> "Regarding the enablement issues and description issues, it is noted that applicants' arguments are directed to claims after proposed amendments would be entered and in view of the non-entry of the proposed amendments these arguments would not be addressed."

The basis for this apparent distinction is unclear, since patent practice stipulates that when new matter is introduced into claims, those claims should be rejected under 35 U.S.C. 112, first paragraph, because the new matter is not described in the application as originally filed (M.P.E.P. §§ 608.04, 706.03[o], 2163.06). Clarification, which might help applicants address any outstanding rejections, is requested in subsequent correspondence.

Respectfully submitted,

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Sarah Elson Reg. No. 50,360

EXELIXIS, INC.
170 Harbor Way
P.O. Box 511
South San Francisco, California 94083-0511
Telephone: (650) 837-8151
Facsimile: (650) 837-8234

APPENDIX A

Page 56 lines 34-36 and page 57 lines 1-7

The presence of other gene and protein sequences bearing significant homology to Drosophila S2P ([Fig.2,] SEQ ID NO.4) was investigated using the BLAST family of computer programs (Altschul et al., supra). The following amino acid sequences were the most similar: S2P Homo sapiens (GI2745733); S2P Cricetulus griseus (GI2745731); SP2 metalloprotease, Homo sapiens (GI4164134 and GI4164135); putative protein Arabidopsis thaliana (GI2982448); conserved protein Methanobacterium thermoautotrophicum (GI2622476); and Orf c04034 Sulfolobus solfataricus (GI1707806). The most homologous sequence was human S2P (GI2745733) which shared 9 contiguous amino acids at positions 201-207 of SEQ ID NO:4. Amino acid 127 to 501 of SEQ ID NO:4 shares 32 % sequence identity with amino acids 148 to 515 of GI2745733.

Page 41 lines 8-19

These reactions, together with sequence from M13 forward and reverse primers, gave a full sequence in both directions that was nearly identical to the posted, unfinished sequence from Y47D3. The cDNA sequence of the ceSREBP gene[,] is provided in SEQ ID NO:1[is shown in Figure 2]. The cDNA is 3419 nucleotides long. This full-length clone contained a single open reading frame with an apparent translational initiation site at nucleotide position 24 and a stop signal at nucleotide position 3365. The predicted polypeptide precursor is 1113 amino acids long. Additional features include an acidic domain at about nucleotides 24 to 233 (amino acid residues 1 to 69); a possible second acidic domain at about nucleotides 987 to 1040 (amino acid residues 321 to 338); a basic Helix-loop-helix domain at about nucleotides 1089 to 1286 (amino acid residues 355 to 421); a first transmembrane domain at about nucleotides 1455 to 1514 (amino acid residues 477 to 497); and a second transmembrane domain at about nucleotides 1653 to 1706 (amino acid residues 543 to 561).